

Amendment No. 2 to HB2505

**Hawk
Signature of Sponsor**

AMEND Senate Bill No. 2124*

House Bill No. 2505

by deleting all language after the enacting clause and substituting instead the following:

SECTION 1. Tennessee Code Annotated, Title 71, is amended by adding the following as a new chapter:

71-7-101. There is established the Tennessee rare disease advisory council, referred to in this chapter as the "advisory council", to advise the TennCare prescription drug utilization review committee, referred to in this chapter as the "DUR", the TennCare pharmacy advisory committee, referred to in this chapter as the "PAC", and other public and private agencies in this state in providing services for persons diagnosed with rare diseases.

71-7-102.

(a) The advisory council is composed of eleven (11) members as follows:

(1) The governor shall appoint:

(A) One (1) representative from the bureau of TennCare;

(B) Two (2) representatives from academic research institutions in this state that receive grant funding for rare disease research;

(C) Two (2) physicians licensed and practicing in this state with experience in researching, diagnosing, or treating rare diseases;

(D) One (1) geneticist or genetic counselor licensed and practicing in this state;

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(E) One (1) registered nurse or advanced practice registered nurse with experience treating rare diseases who is licensed and practicing in this state;

(F) One (1) resident of this state who is eighteen (18) years of age or older and who:

(i) Has been diagnosed with a rare disease; or

(ii) Is a caregiver for a person who has been diagnosed with a rare disease; and

(G) One (1) representative of a rare disease patient organization operating in this state; and

(2) The speaker of the senate and the speaker of the house of representatives shall each appoint one (1) member to the advisory council.

(b) In order to stagger the terms of the newly appointed advisory council members:

(1) The persons appointed under subdivisions (a)(1)(A) and (B) serve initial terms of one (1) year, which expire on June 30, 2021;

(2) The persons appointed under subdivisions (a)(1)(C)-(E) serve initial terms of two (2) years, which expire on June 30, 2022; and

(3) The persons appointed under subdivisions (a)(1)(F), (a)(1)(G), and (a)(2) serve initial terms of three (3) years, which expire on June 30, 2023.

(c)

(1) Following the expiration of the initial terms, all appointed members of the advisory council serve terms of three (3) years.

(2) Members of the advisory council shall serve until their successors have been appointed, with vacancies to be filled in the same manner as provided in the original appointments.

(d) In making appointments to the advisory council, the appointing authorities shall strive to ensure that the advisory council is composed of persons who are diverse in professional or educational background, ethnicity, race, age, sex, geographic residency, heritage, perspective, and experience.

(e) The advisory council members receive no compensation for their services on the advisory council.

(f)

(1) The advisory council shall meet quarterly, and may meet more often as determined by a majority vote of the advisory council. A member may participate in an advisory council meeting by teleconference up to two (2) times each calendar year.

(2) The governor shall call the initial meeting of the advisory council no later than October 1, 2020, for the purpose of electing a chair, vice chair, and secretary. The council is solely the administrative responsibility of the chair, and all subsequent meetings of the council must be called in accordance with this subsection (f). The bureau of

TennCare is responsible only for submitting minutes compiled by the advisory council to the PAC and the DUR.

71-7-103.

(a)

(1) The Tennessee rare disease advisory council shall advise the DUR, the PAC, and other state entities in their review of products or medications for the treatment of rare and orphan diseases, and drugs or biological products within the emerging fields of personalized medicine and non-inheritable gene editing therapeutics.

(2)

(A) All advisory council recommendations must be presented in writing to members of the PAC and DUR and explained to members of the PAC and DUR by representatives of the advisory council during their public meetings.

(B) The advisory council has no authority on any matter relating to TennCare, nor may it require the DUR or PAC to follow its recommendations.

(b) The DUR and PAC shall consider information submitted to them by the advisory council on rare diseases and personalized medicine when making recommendations or determinations regarding:

(1) Beneficiary access to drugs and biological products for rare diseases, as defined in the federal Orphan Drug Act of 1983 (21 U.S.C. §§ 360aa - 360ff-1);

(2) Drugs and biological products that are approved by the United States food and drug administration; and

(3) The emerging fields of personalized medicine and non-inheritable gene-editing therapeutics.

(c) The DUR and PAC shall seek the input of the advisory council on rare diseases and personalized medicine to address topics for consultation under this chapter, including, but not limited to:

(1) Rare diseases;

(2) The severity of rare diseases;

(3) The unmet medical needs associated with rare diseases;

(4) The impact of particular coverage, cost-sharing, tiering, utilization management, prior authorization, medication therapy management, or other medicaid policies on access to rare disease therapies;

(5) An assessment of the benefits and risks of therapies to treat rare diseases;

(6) The impact of coverage, cost-sharing, tiering, utilization management, prior authorization, medication therapy management, or other medicaid policies on patients' adherence to the treatment regimen prescribed or otherwise recommended by their physicians;

(7) Whether beneficiaries who need treatment from or a consultation with a rare disease specialist have adequate access and, if not, what factors are causing the limited access; and

(8) The demographics and the clinical description of patient populations.

(d) Nothing in this chapter requires the advisory council, the DUR, or the PAC to consult with a person on any matter or requires those entities to meet with any specific expert or stakeholder.

SECTION 2. Tennessee Code Annotated, Section 4-29-243(a), is amended by adding the following new subdivision:

() Tennessee rare disease advisory council, created by § 71-7-101;

SECTION 3. For the purpose of appointing members to the Tennessee rare disease advisory council, this act shall take effect upon becoming a law, the public welfare requiring it. For all other purposes, this act shall take effect July 1, 2020, the public welfare requiring it.